In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-51V

UNPUBLISHED

JANE BRENNOM, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: October 6, 2023 Special Processing Unit (SPU); Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA); Six Month Severity Requirement

Jessica Anne Olins, Maglio Christopher & Toale, PA, Seattle, WA, for Petitioner.

Christine Mary Becer, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION DISMISSING CASE[1]

On January 5, 2021, Jane Brennom filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that she suffered a shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine administered on January 16, 2019. Petition at 1-2.

On June 14, 2022, Respondent filed Rule 4(c) Report opposing compensation, arguing (among other things) that Petitioner cannot meet the Vaccine Act's "severity" requirement. An Order was issued requiring Petitioner to show cause why this claim should not be dismissed for failure to establish injury severity. Order to Show Cause, ECF No. 33. Petitioner responded on October 11, 2022. Petitioner's Response to Order to

[1] In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access..

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Show Cause and Motion for Findings of Fact and Conclusions of Law Regarding Severity ("Response"), ECF No. 39.

For the reasons discussed below, I find Petitioner has not established that she suffered the residual effects of her injury for more than six months, and therefore dismissal of the claim is warranted.

I. Procedural History

Shortly after filing her Petition, Ms. Brennom filed declarations from herself and her husband, plus the medical records required by the Vaccine Act. Exhibits 1-16, ECF Nos. 6-8, 10; *see* Section 11(c). On March 18, 2021, the case was activated and assigned to the Special Processing Unit. ECF No. 11.

Respondent filed his Rule 4(c) Report a year later, opposing compensation because of an inability to show severity. Rule 4(c) Report at 1-2 (citing Section 11(c)(1)(D)). In particular, given an intervening left arm injury from a blood draw and a year-long gap in treatment from early June 2019 (less than five months post-vaccination) until late June 2020 (more than one year later), "[i]t cannot be assumed that the shoulder pain reported on June 30, 2020, was related to her flu vaccine on January 16, 2019." *Id.* at 5. Petitioner maintains in reaction that she can establish severity. Response at 21.

II. Factual Background

The medical records reveal that Petitioner was sixty seven years old at the time of vaccination, and had previously suffered from conditions including osteoarthritis involving multiple joints, herpes zoster without complication, type 2 diabetes, psoriasis, basal cell carcinoma, obesity, cervical stenosis, frozen shoulder, and shoulder bursitis. *See*, *e.g.*, Ex. 6 at 23-24; Ex. 16 at 49; Ex. 11 at 5. She underwent multiple surgeries including three right shoulder arthroscopic surgeries in 2011 through 2013. Ex. 6 at 24; Ex. 11 at 6. Petitioner was regularly seen by a rheumatologist for her osteoarthritis, the symptoms of which included fatigue, swelling in the knees and fingers, and pain in the lower back, knee, toes, neck, and shoulders. Ex. 6 at 5 (August 6, 2018 rheumatology visit). In her affidavit,

On January 16, 2019, Petitioner received a flu vaccine in her left arm. Ex. 17 at 7. Twice later that winter - on January 22, 2019, and February 4, 2019 - Petitioner saw her rheumatologist, but did not report shoulder pain. Ex. 6 at 30-37, 49- 51. But she reported the pain at a subsequent rheumatology visit on February 21, 2019.

An MRI of Petitioner's left shoulder performed on March 4, 2019, revealed a partial thickness supraspinatus tear, moderate infraspinatus and teres minor muscle edema, a

SLAP tear that was "likely degenerative", mild osteoarthritis, mild subacromial and subdeltoid bursitis, and "severe infraspinatus tendinopathy". Ex. 6 at 57. The muscle edema and bursitis were noted as possibly related to the injection. *Id.* There were also signs of severe infraspinatus tendinopathy, moderate infraspinatus and teres minor muscle edema. *Id.*

On March 25, 2019, Petitioner returned to her rheumatologist who noted that the MRI showed inflammation and bursitis "possibl[y] related to the injection site" or early brachial plexus neuropathy. Ex. 6 at 40-45.

Petitioner was next seen by Dr. Mark Frankle at the Florida Orthopaedic Institute on April 10, 2019, for left shoulder pain, which she reported had begun at the time of her January vaccination. Ex. 2 at 8. A physical exam showed mild to moderate range of motion restrictions but full strength. Ex. 2 at 10-12. She was diagnosed with a SIRVA and a cortisone injection was administered. *Id.* at 12.

Several months later, on June 4, 2019, Petitioner returned to Dr. Frankle and reported 75% improvement. Ex. 2 at 6. Dr. Frankle now noted that Petitioner "has made excellent gains both subjective[ly] and objectively since her last visit", but that she wanted to try another injection. *Id.* A second cortisone injection was administered at that time. *Id.* at 6-7.

After a three-month gap in treatment, Petitioner saw her primary care provider, Dr. Beth Belof-Jasko, on August 6, 2019. Ex. 16 at 91. The record notes that Petitioner had "complication of flu shot- bursitis of left shoulder this past winter," but includes no mention of ongoing or existing pain. *Id.* Then, after a lengthier gap, Petitioner returned to her primary care physician in February 2020 - but for left elbow pain. Ex. 16 at 139. She now reported that she had blood drawn three weeks prior and her left elbow has been sore and tender since that time. She again made no mention of her prior SIRVA concerns.

After yet another treatment gap (and now and 18 months post-vaccination), Petitioner returned to Dr. Frankle on June 30, 2020, complaining of left shoulder pain and seeking another steroid injection. Ex. 2 at 14. She now reported her pain as eight out of ten at that time, and another cortisone injection was administered. *Id.* at 15-16. She was assessed with an inflamed rotator cuff with a history of an underlying vaccination causing the need to treat.

A year later (June 2, 2021), she returned to orthopedist for a follow-up regarding her left shoulder. Ex. 18 at 8-10. She reported that she was still experiencing shoulder pain, and rated it as eight out of ten. *Id.* at 9. Further, Petitioner gave "a history of having

had a vaccine Administration into her left arm" and "feels she is currently having a flare up." *Id.* An examination showed impingement symptomatology, but no reduced range of motion. *Id.* at 10.

Petitioner was again seen for shoulder pain on August 3, 2022. Ex. 23 at 12-14. The record notes that Petitioner "has been having pain in her shoulder for a couple of years." *Id.* at 14. She was diagnosed with tendinitis and mild-to-moderate degenerative changes. Petitioner had a follow-up for her shoulder pain on September 14, 2022. Ex. 23 at 7. The record notes that Petitioner's shoulder pain was "secondary to a flu vaccine given in her left deltoid in 1/2019 resulting in post vaccine bursitis vs post vaccine tendonitis." *Id.* at 9.

Petitioner returned to Florida Orthopaedic Institute on September 14, 2022, with complaints of pain in her left shoulder and tendinitis of the left rotator cuff. Ex. 23 at 13. The record states on set of the left shoulder pain was June 4, 2019, and tendinitis onset was August 5, 2022. *Id.*

Petitioner has submitted three affidavits in support of her petition. Ex. 12, 14, 20. She states that her arm pain started immediately after the injection. Ex. 14 at 1. Petitioner further described how the pain has affected her life and her course of treatment. *Id.* at 1-3. She also described how Covid impacted her ability to seek treatment, indicating that the gaps in treatment were due in part to a desire to avoid Covid exposure. Ex. 20 at 2.

Stephen Brennom, Petitioner's husband, also submitted an affidavit in this case. Ex. 13. Mr. Brennom states that Petitioner first complained of shoulder pain the day after she got vaccinated, and that she became frustrated when local providers could not identify a reason for her pain. *Id.*

Petitioner also submitted an expert report addressing causation and sequela. Ex. 24.

III. Legal Standard

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding her claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

In particular, a petitioner must establish that she suffered an injury meeting the Table criteria (*i.e.* a Table injury), in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. If a petitioner establishes a Table injury the burden shifts to respondent to establish a more likely alternative cause. Section 13(a)(1)(A), 11(c)(1)(C)(i), 14(a). If a petitioner cannot establish a Table injury, she or she may pursue causation-in-fact under the legal standard set forth in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F. 3d 1274, 1278 (Fed. Cir. 2005).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (*e.g*. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

In addition to causation, a petitioner must also meet the requirements establishing that the vaccine received is "covered" by the Program, the duration and severity of petitioner's injury, and the lack of other award or settlement.[3] With regard to

[3] In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* § 11(c)(1)(A)(B)(D)(E).

severity, a petitioner must show that she suffered the residual effects or complications of her injury or condition for more than six months after the administration of the vaccine. § 11(c)(1)(D)(i); *see Song v. Sec'y of Health & Hum. Servs.,* 31 Fed. Cl. 61, 65-66 (1994), aff'd, 41 F.3d 1520 (Fed. Cir. 2014) (noting that a petitioner must demonstrate the six-month severity requirement by a preponderance of the evidence). Finding that petitioner has met the severity requirement cannot be based on petitioner's word alone, though a special master need not base their finding solely on medical records. Section 13(a)(1); *see Colon v. Sec'y of Health & Hum. Servs.*, 156 Fed. Cl. 534, 541 (2021). Severity must be established regardless of whether the claim arises under the Table or is a causation-in-fact claim.

IV. Petitioner Does Not Meet the Severity Requirement

Petitioner received her vaccine on January 16, 2019, and alleges pain that same day. To meet the severity requirement, she must establish that she suffered the effects of her injury through July 16, 2019 (six months after onset). The record in this case, however, establishes pain only through early June 2019, less than five months post-vaccination. Ex. 2 at 6. Thereafter it is silent for over one year – or until June 30, 2020. *Id.* at 13-14. Thus, the record supports only the premise that Petitioner's left shoulder injury lasted through early June 2019 – less than five months post- vaccination.

Other record evidence corroborates the conclusion that Petitioner's injury more likely than not had resolved within the six month post-onset period. After receiving her first steroid injection in early April 2019, Petitioner reported 75 percent improvement. Thus, it is reasonable to believe that the second steroid injection administered in early June 2019 likely offered a complete resolution of any remaining vaccine induced pain.

There is other evidence suggesting a recurrence of pain – but it occurs too long after the six-month severity timeframe to conclude it was "more likely than not" related to the SIRVA, as opposed to some other intervening event. Thus, although Petitioner again reported left shoulder pain in June 2020, she has not provided sufficient evidence to link this later pain to her January 2019 injury. The MRI, performed in March 2019, showed multiple conditions which could account for Petitioner's later pain – such as the SLAP tear attributed to degenerative changes. And the record clearly establishes that Petitioner suffered prior shoulder problems - including a frozen left shoulder in 2000 and osteoarthritis and pain in multiple locations – including her shoulders.

Petitioner also argues that the gap in treatment was due to the effectiveness of the cortisone injections. Response at 10-12. The gaps in this case, however, are not short or only occurring after receipt of a cortisone shot. Rather, there are three between

treatments, with each lasting months to a year.[4] Based upon my experience adjudicating thousands of SIRVA claims, it would be unusual for a steroid injections to provide such lengthy periods of otherwise-temporary relief for a SIRVA injury that was persisting.

Given the above, I cannot conclude that the record preponderantly establishes Petitioner's injury persisted for the six months required by the Act. Such lengthy treatment gaps are too large to ignore in this case given the facts, and allows for the possibility of other intervening factors as more likely explanatory of Petitioner's subsequent shoulder complaints than her winter 2019 injury.

Conclusion

Because Petitioner has failed to meet the severity requirement set forth in Section 11(c)(1)(D)(i), Petitioner cannot establish entitlement, and therefore I must **DISMISS** his claim in its entirety. In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk of Court shall enter judgment in accord with this Decision.[5]

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[4] Petitioner did not seek treatment or report shoulder problems during the following periods: June 4, 2019 to June 30, 2020; June 30, 2020 to June 2, 2021; and June 2, 2021 to August 3, 2022.

[5] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.